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EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,130	LAWSON, CHRISTOPHER PATRICK	
	Examiner	Art Unit	
	Navin Natnithithadha	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claim 1 has been amended. Claims 6-12 have been cancelled. Claims 1-5 are pending.

2. The 35 U.S.C. 112, second paragraph, rejections to claims 6-12 are WITHDRAWN in view of the Amendment, filed on 07 June 2007.

3. Applicant amended the paragraph at page 2, lines 11-21, of the Specification.

Specification

4. The amendment filed 07 June 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

In the Amendment, filed on 07 June 2007, Applicant amended paragraph at page 2, lines 11-21, by inserting the limitation "wherein at least one of the lateral aperture positioned in the wall of the cylindrical member and the lateral aperture positioned in the wall of the sleeve is of a triangular shape". Although one alternative of the limitation, i.e. "the lateral aperture positioned in the wall of the sleeve is of a triangular shape", is supported by the Applicant's original disclosure, filed on 10 September 2003, on page 8, lines 7-11, and Figure 4 (see triangular shaped orifice 44 and sleeve 52), the other alternative of the limitation, i.e. "the lateral aperture positioned in the wall of the

cylindrical member…is of a triangular shape", is not supported by the original disclosure because the scope of Applicant's original disclosure only covers an orifice 44 of triangular shape positioned in the wall of the sleeve 52.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the Amendment, filed on 07 June 2007, Applicant amended claim 1 by inserting the limitation "wherein at least one of the lateral aperture positioned in the wall of the cylindrical member and the lateral aperture positioned in the wall of the sleeve is of a triangular shape". Although one alternative of the limitation, i.e. "the lateral aperture positioned in the wall of the sleeve is of a triangular shape", is supported by the Applicant's original disclosure, filed on 10 September 2003, on page 8, lines 7-11, and Figure 4 (see triangular shaped orifice 44 and sleeve 52), the other alternative of the limitation, i.e. "the lateral aperture positioned in the wall of the cylindrical member…is of

a triangular shape", is not supported by the original disclosure because the scope of Applicant's original disclosure only covers an orifice 44 of triangular shape positioned in the wall of the sleeve 52.

Claims 2-5 are rejected because of their dependency, directly or indirectly, to claim 1.

In addition, for the purpose of clarity, the Examiner suggests the use of paragraphs, indentations, colons, and semicolons to distinguish between the limitations of the claimed apparatus.

Claim Objections

6. Claims 2-4 are objected to because of the following informalities:

Claims 2 and 3 recites the limitation "microprocessor control means" in claim 2, lines 4-5, and claim 3, lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the phrase "and/or", and thus, makes the claim indefinite as to whether both the claim requires the "display screen" and the "hard copy print device".

Appropriate correction is required.

Response to Arguments

7. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

Applicant introduced new matter into claim 1 in the Amendment, filed on 07 June 2007, which changed the scope of the claims from the previously presented claims, filed

on 11 January 2007. Because the amendment to the claims required a new consideration and search, the present Office Action is made FINAL.

In addition, Applicant contends, see Applicant's Remarks, pp. 5-6, filed on 07 June 2007, the following:

> This triangular shape is not shown in either Holscher or in Hillsman. In particular, the main citation of Holscher discloses only rectangular apertures. Rectangular apertures do not give fine control, The Applicant requires fine control and this is provided by the stated triangular shape. The triangular shape importantly gives good fine control at low flows as occur at the end of a person breathing into the mouthpiece. This would not be able to be achieved by the Holscher rectangular apertures, If Hillsman is combined with Holscher as suggested by the Examiner, then the new feature inserted into the Applicant's claim 1 is still not achieved.

However, this argument contradicts the Applicant's original disclosure, filed on 10 September 2003. On page 4 of the Applicant's Specification, Applicant's discloses the following (emphasis added):

> The rotary variable orifice valve may have an orifice which is of a shape that causes the resistance to flow of the rotary variable orifice valve to increase with rotation. Preferably, the orifice in the rotary variable orifice valve is of a triangular shape. *Other shapes may be employed if desired*.

On page 8 of the Applicant's Specification, Applicant's discloses the following (emphasis added):

> The rotary variable orifice valve 42 comprises a cylindrical member 46 having a bore 48 and *a rectangular aperture 50*. The orifice 44 is in a sleeve 52 which is a rotational fit over the cylindrical member 46. As shown in FIG. 4, the cylindrical member 46 is in the form of a short tube. During use of the rotary variable orifice valve 42, the sleeve 52 rotates over the cylindrical member 46, and the orifice 44 overlaps by varying amounts the *rectangular aperture 50*. In this way, the effective size of the orifice 44 is varied.

Nowhere in the original disclosure does the Applicant disclose that the triangular shape provides an advantage, is used for a particular purpose, or solves a stated problem. In fact, the Applicant explicitly discloses that "[o]ther shapes may be employed if desired" (see page 4).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holscher, U.S. Patent No. 5,630,411 A ("Holscher"), in view of Hillsman, WO-98-14115 A1 ("Hillsman"), and further in view of Minowa et al, U.S. Patent No. 4,909,212 A ("Minowa").

Claims 1: Holscher teaches an apparatus (see figs. 1 and 5-8), comprising: a mouthpiece (inlet tube) 20/130; a flow transducer 18; a pressure transducer 16; a rotary variable orifice valve 14; a motor (valve motor) 78; and a microprocessor controller 26, wherein the microprocessor controller/circuit 26 controls the motor to cause the rotary variable orifice valve 14 to vary its orifice size in response to at least one of flow and pressure signals obtained consequent upon the person breathing into the mouthpiece (see col. 4, ll. 60-65), wherein the orifice size maintains a constant predetermined pressure (controller 26 receives signals from phase detection circuit 24, which receives a signal from the flow sensor, see col. 4, ll. 60-65) and enables measurement of the flow rate or pressure generated by the person and enables measurement of the flow rate

generated by the person (matter of intended use of rotary variable orifice valve 14), and wherein the variable orifice valve 14 is a rotary variable orifice valve 14 comprising a cylindrical member (shiftable valve element, which includes support bodies 114 and valve fingers 116) 72, a longitudinally extend bore (motor shaft) 80 in the cylindrical member 72, a first lateral aperture (exhaust ports) 122 positioned in a wall of the cylindrical member 72 and between ends of the cylindrical member 72, a sleeve (structure including the valve base 70 and valve element cover 74) 70/74, a longitudinally extending bore (upper section) 82 in the sleeve 70/74, and a second lateral aperture (recesses) 96 positioned in a wall of the sleeve between ends of the sleeve.

In the alternative, although "enables measurement of the flow rate or pressure generated by the person and enables measurement of the flow rate generated by the person" is a matter of intended use of Holscher's rotary variable orifice valve 14, Hillman teaches this subject matter (see pg. 14, ll. 2-6, and pg. 15, ll. 1-6). It would have been obvious to one of ordinary skill in the art to modify Holscher's rotary variable orifice valve to be used in Hillman's respiratory testing apparatus in order to control breathing conditions for monitoring a patient's respiratory parameters (see Hillman, Abstract).

As for the limitation "wherein at least one of the lateral aperture positioned in the wall of the cylindrical member and the lateral aperture positioned in the wall of the sleeve is of a triangular shape", which is considered new matter (see the 35 U.S.C. 112, first paragraph, rejection above), Horscher teaches the lateral aperture 96 is of a

rectangular shape (see fig. 5), which, according to Applicant's original disclosure, on page 4, a rectangular shape aperture/orifice is an equivalent structure.

Neither Horscher nor Hillsman teach a that a lateral aperture is of a triangular shape. However, Minowa teaches a valve apparatus structurally similar to Horscher and Hillsman, comprising a triangular shaped lateral aperture 17 of cylindrical section 15 (see figs. 9A, 9B, and 22A). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Horscher's aperture 96 to have a triangular shape because, according to Minowa, a triangular aperture (17) varies the opening (orifice) continuously, and "with such an arrangement, there is provided such an advantage that, even if the control accuracy of the motor serving as a source of operation driving force for the valve is coarse, the control accuracy of the air flow rate flowing can be secured sufficiently" (see Minowa, col. 11, ll. 13-23).

Claims 2-4: Holscher does not teach "a control circuit, the flow transducer being connected to the control circuit, the pressure transducer being connected to the orifice valve and to the control circuit, and the control circuit being connected to the microprocessor control means". Hillsman teaches an apparatus (see fig. 2), comprising: a mouthpiece (not labeled); a flow transducer 4; a pressure transducer 5; a flat plate or rotary variable orifice valve 3 (see figs. 3A, 3B, 3C); a motor 28; a display 6 and a microprocessor controller/control circuit (computer) 14, the microprocessor controller/control circuit 14 being connected to the pressure transducer 5 and flow transducer 4. It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Holscher's microprocessor controller 26, pressure

transducer 16, flow sensor 18, and orifice valve 14 to be connected to Hillsman's control circuit 14 in order to obtain, process and display respiratory data to the user of the device, such as the data shown in Figure 3 of Holscher.

Although Holscher does not explicitly teach a display means, a keyboard, and a display screen or hard copy print device, Hillsman teaches a personal computer 14, which is known in the art to comprise a display and a keyboard, connected to a pressure transducer 5, flow transducer 4 and a variable orifice 3 (see fig. 2). It is obvious to one of ordinary skill in the art to modify Holscher's pressure controller 26 to include a display and a keypad/keyboard in order to operate Holscher's apparatus. In addition, these features do not appear critical to the Applicant's invention.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holscher, as applied to claim 1 above, and further in view of either Bacaner et al, US 4,966,141 (hereinafter referred to as Bacaner).

Claim 5: Holscher does not teach the mouthpiece (inlet tube) 20/130 has a flange. However, Bacaner teaches a disposable mouthpiece 200 including a flange 203 (see fig. 19 and col. 19, lines 52-53). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Jiang's mouthpiece to include flange as taught by Bacaner in order to provide a disposable mouthpiece that effectively engages the face of the patient surrounding the mouth (see Bacaner, col. 19, lines 55-57).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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11/19/2007

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